Judith Robinson
Professional Staff Member
Subcommittee on Employment, Poverty
and Migratory Labor

MAY 26 1978

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Sen Nelson

May 22, 1978

Professor Joshua Lederberg
Department of Genetics
Stanford University School of Medicine
300 Pasteur Drive
Palo Alto, California 94304

Dear Dr. Lederberg,

Thank you very much for taking the time to meet with me and to have lunch with us while I was at Stanford May 10. I appreciate your sending the article on laboratory practices and your statement on DNA research, which I shared with Senator Stevenson's staff and other Senate staff.

It is anticipated that a letter signed by several Senators will be sent to HEW shortly, inquiring about existing statutory authority as a mechanism for monitoring DNA research. I specifically have included reference, per your suggestion, to the FDA's authority to require compliance with NIH guidelines by private industry. Enclosed is a page from a letter to Sen. Stevenson from Secy. Califano following the Senate Commerce Science Subc. hearings last Nov. on DNA, in which this matter is addressed.

I also appreciate receiving your draft language and thoughts on Delaney.

We'll be in further touch, and let us know if we can assist you in any way,

Sincerely,
Judith Robinson

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section 361 to regulate a number of products including shellfish, pet turtles, primates, and human blood. Our Office of the General believes it is preferable for a regulatory effort required to oversee all recombinant DNA activities, or not known to affect human health, to be based on the explicit support of the Congress as well as that of the Administration, particularly in light of the active interest the Congress has shown in this area. The consensus needed for this type of program is not best established by applying a general provision of law to this specific situation.

2. Other HEW Authorities

The Food and Drug Administration (FDA) is responsible for assuring that human drugs, biologics, medical devices, foods, cosmetics, and animal drugs, are safe, effective, and are produced in conformity with good manufacturing practices. For all new drugs, new animal drugs, biologics, food additives and color additives, and medical devices, the sponsor or manufacturer has the burden of demonstrating the safety and efficacy of products proposed for marketing. The Federal Food, Drug, and Cosmetic Act requires manufacturers of such products to submit safety and efficacy data supporting their petitions to FDA for review and approval before the product is introduced into interstate commerce.

The FDA has responsibility to safeguard the public from all potential hazards that may result from the development of products that are subject to the Agency's jurisdiction. This authority would extend to research on regulated products where recombinant DNA is involved. The Agency could, under existing authority, require any firm seeking approval of a product which may be the end product of recombinant DNA research to certify to the Agency that it has complied with the National Institutes of Health (NIH) Guidelines on recombinant DNA. For example, certification could be required for biologics, requests for certification could be required in petitions, such as new drug applications, license applications for biologics, requests for certification of antibiotics, and notices of claimed investigational exemption of a new drug. In addition, FDA under its investigational authorities may inspect firms making such certification to assure that they do, in fact, comply with the NIH guidelines. The Agency does have a number of regulatory sanctions it could bring to bear on any firm not in compliance with the Guidelines. These range from a denial of the petition to court actions.

John — maybe one of FDA Q. would refer to this observation by Califano in his letter to AES.

FROM: Letter to Sen. Stevenson from Sen. Califano following Stevenson DNA hearings in NOV., 77.